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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,618	12/07/2004	Steven Melvyn Howdle	P70039USD	4009

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

HELM, CARALYNNE E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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04/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,618

Applicant(s)

HOWDLE ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-59 is/are pending in the application.
- 4a) Of the above claim(s) 28,30,31,34-36,38,41,44,46,47,50-52,54 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-27,29,32,33,37,39,40,42,43,45,48,49,53,55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-846)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/2/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I where the species includes deposition of dissolved/dispersed material by immersion and the deposit material is drugs and pharmaceutical products in the reply filed on January 8, 2009 is acknowledged. The traversal is on the grounds that the Liquid State Activation reference does not teach the common technical feature in the invention, specifically the step of drying by freezing evaporation, heating or blotting. This is not found persuasive because the reference teaches the application of a solution of drug in a solvent to a polymer. After treatment with supercritical CO₂ and depressurization, solvent vapors are contained in the gas stream of CO₂ that is extracted from the polymer. Since the solvent starts as a liquid and is then removed as a gas, this process constitutes drying by evaporation. Therefore the Liquid State Activation reference does teach each step of the process that is the common technical feature of the inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28, 30-31, 34-36, 38, 41, 44, 46-47, 50-52, 54, and 57-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Objections

Claims 25 and 42 are objected to because of the following informalities: these claims recite a series of steps that are not separated by appropriate punctuation or delineations to make the beginning and end of the recitations for each step clear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-40 and 55-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as nerve growth factor, bone morphogenic protein, and doxorubicin which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 39-40 and 55-56 are directed to encompass function enhancing components, otherwise modified growth promoters, biocompatibilisers, human and animal health products, functioning matter, and products intended for growth or repair or modeling of the skeleton, organs, dental structure which only correspond in some undefined way to specifically instantly

disclosed chemicals. The "deposition materials" recited above do not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are, the variability in the possible chemical structures as well as the lack of connection between the structure and function claimed. The specification provides insufficient written description to support the genus encompassed by the claim and the prior art does not provide sufficient description to supplement the omission.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The lack of description provided in the specification for the structures that correspond to the claimed functions do not allow the skilled artisan to envision the detailed chemical structure of the encompassed "deposition materials". In addition, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemicals, but not the full breadth of the

claims meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 27, 29, 40, 42, and 56 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites a deposition layer that is "intact to solvent and impact effects". It is not clear what constitutes an "impact effect". Further the wording of the limitation is awkward and difficult to understand.

Claim 29 recites deposition matter on an "internal and external exposed surface"; however the limitations of this recitation are not clear since what constitutes an "exposed surface" is not clearly defined.

Claim 42 recites a string of limitations in the alternative that make it unclear which options correspond to a particular recitation. Specifically, the options for the step of drying appears to include freezing, evaporation, heating, blotting, and solid phase deposition by powder coating, dusting, rolling or adhering.

Regarding claims 40 and 56, the phrase "such as" as well as "and the like" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "high" in claims 27 and 43 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 27, 29, 32-33, 37, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perman et al. (US Patent No. 5,340,614).

The instant claims recite a method of preparing a polymer composite. Perman et al. teach the claimed method where a carrier fluid is combined with an impregnation material (deposition materials) and applied to a polymer such that the polymer is covered (see column 4 lines 43-50). A supercritical fluid is added to the system, swelling the polymer and impregnating the impregnation material into the polymer (see column 3 line 52-column 4 line 13; instant claim 27). The supercritical fluid is then removed from the system (see column 4 lines 8-13). Biologically active drugs, including nucleotides, vitamins, and proteins, are particularly preferred impregnation materials (see column 6 line 61-column 7 line 4; instant claims 39-40). In addition, Perman et al. teach the drying of the carrier fluid from the impregnated polymer by blotting (see column 17 lines 3-7). Since the impregnation material is retained after this "impact" and coats, at least at

a molecular level, the surface of polymer strands, the limitations of "deposition matter adsorbs from liquid phase on to the polymer surface on to the polymer surface and forms an adsorption layer of deposition matter which is intact to solvent and impact effects" are met (see instant claims 25 and 29). According to MPEP 2111.01 II, "it is improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order." Neither the specification or the recitation of the claims strictly require a specific order for the steps in the method, therefore the teachings of Perman et al. meet the limitations of the claimed process (see instant claim 25). In addition, the absence of agitation is taught by Perman et al. when a solution of impregnation material is employed (see column 10 lines 26-31; instant claim 37). Perman et al. also teaches the immersion of the polymer in the impregnation material and carrier fluid for 17 hours (see column 16 line 66-column 17 line 5; instant claim 32). Therefore claims 25, 27, 29, 32-33, 37, and 39-40 are obvious over Perman et al.

Claims 25, 26, 42-43, 45, 48-49, 53, and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perman et al. as applied to claims 25, 27, 29, 32-33, 37, and 39-40 above, and further in view of Colombo et al. (US Patent No. 6,913,779).

Perman et al. makes obvious the method as recited in claims 25 and 42 as well as the details of the recited dependent claims 43, 45, 48-49, 53, and 55-56 but does not teach the relative amount of impregnated material on the polymer.

Colombo et al. teach a method of impregnating a polymer with a drug using a carrier fluid and supercritical fluid in a process as taught by Perman et al. (see column 3 lines 38-49 and column 5 lines 3-5). Colombo et al. goes on to teach a 1:10 to 1:1 ratio of active to polymer in the impregnated material (see column 4 lines 49-55; instant claims 26 and 42). Therefore it would have been obvious for one of ordinary skill in the art at the time of the invention to use the teachings of Colombo et al. to determine the proportion of impregnation material to include in the polymer of Perman et al. Thus claims 25, 26, 42-43, 45, 48-49, 53, and 55-56 are obvious over Perman et al. in view of Colombo et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635